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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/454,252	12/02/1999	JERRY PELLETIER	248/037	3544

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EXAMINER	
MITRA, RITA	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Advisory Action	Application No. 09/454,252	Applicant(s) PELLETIER ET AL.	
	Examin r Rita Mitra	Art Unit 1653	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *12 June 2002*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *NONE*.

Claim(s) objected to: *NONE*.

Claim(s) rejected: *100-115*.

Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Continuation of 5.

In regard to the rejection of claims 100-115 under **35 U.S.C. 112, first paragraph**, Applicants' statement at page 3, which reads as "it appears that the Examiner would require a cookbook description for each possible assay and detailed structural information for each possible bacteriophage-encoded inhibitor polypeptide and for each bacterial target" has been noted. Further Applicants argue that such a view is unsuitable for the subject matter claimed, ignoring the general applicability of methods, the standard technical knowledge possessed by one of ordinary skill in the art, and the guidance provided in the present specification. Applicants' comments are noted but found unpersuasive because the specification fails to describe at least a single specific assay and a detailed structural information for at least a single variant of a bacteriophage-encoded inhibitor polypeptide and for at least a single bacterial target. The general applicability of the methods and the standard technical knowledge possessed by one of ordinary skill in the art is not adequate to enable the claimed invention without undue experimentation. Applicants assert that the description of the present claims is demonstrated in US patent 6,376,652. However, it should be noted that the '652 was issued on April 23, 2002 (filing date December 22, 1999) and final rejection was made on March 12, 2002. The specification should not omit a description in lieu of a description appearing in the post filing date publication (the filing date of the instant application is December 2, 1999). Moreover, the '652 does not support the enablement for the bacteriophage polypeptide fragments.

Regarding claims 101-105 and 107-115 Applicants do not separately address the rejection of these claims under 112, first paragraph, therefore as stated in the previous office action the claims remain rejected for the reasons given below:

Claim 101 is directed to a method wherein the binding is determined using affinity chromatography on a solid matrix. Specification fails to provide a specific description for the condition of the assay for the binding of bacteriophage polypeptide to the bacterial target protein. It is unclear how affinity chromatography as recited, "identifies a protein" without steps effecting "identification", i.e. comparison of something.

Claims 102-105 and 115 are directed to a method identifying a bacterial target protein that binds to a fragment of bacteriophage polypeptide. No biological activities were attributed to the recited protein fragments and the structural information was limited. There is no disclosure about the binding activities of claimed fragments. Applicants assert on page 8, lines 3-8 of response (paper #13) that using the procedure described in the present application 6 proteins derived from phage 77 were identified which inhibit bacterial growth in solid and liquid assays. Identification of these inhibitor ORFs is described in the specification of the parent application 09/407804 and also in PCT Publication WO 0146383, however none of the references provides any description or demonstration of a method identifying a bacterial target protein that binds to a fragment of bacteriophage polypeptide. It would require undue experimentation for a person having ordinary skill in the art to be able to practice the claimed invention because no guidance has been provided such that a person having ordinary skill in the art would know the structure with reference to the binding site of any fragment of the bacteriophage polypeptide. There is no description given for a binding assay wherein it demonstrates the binding of a fragment of bacteriophage polypeptide to a bacterial target protein. The nature of the invention relates to the generation of any sequence encoding bacteriophage inhibitor protein but no indication has been made as to what activity the encoded protein must have. Applicants' arguments on page 9 lines 6-10 (paper #13) have been noted but not found persuasive. Applicants assert that the "activity" of the encoded phage ORF product is described as 'an ability to inhibit bacterial growth using standard laboratory procedures. However the specification fails to demonstrate any fragment of bacteriophage protein that has ability to inhibit bacterial growth. Therefore, undue experimentation would be required to make and use the claimed protein fragments.

Claim 114 is directed to a method identifying a fragment of bacterial target protein to which said bacteriophage polypeptide binds. No biological activities were attributed to the recited protein fragments and the structural information was limited. Specification fails to provide a specific description for the condition of the assay for the binding of a fragment of bacterial target protein to bacteriophage inhibitor protein. There is no disclosure about the binding activities of claimed fragments. A partial proteolytic fragment of DnaI interacting with the 77ORF104 was demonstrated in WO 01/46383 (page 59, Example 3). However, this demonstration does not reasonably provide enablement for any method for identifying any

fragment of bacterial protein, having any structure or any variation to which any bacteriophage polypeptide binds.

Claims 107-113 are directed to a method of identifying a bacterial target protein that binds to a bacteriophage polypeptide, wherein, said determining is performed for a plurality of bacteriophage polypeptides that inhibit bacterial growth (claims 107-111), bacterial targets (claim 112) and different bacteria (claim 113). The specification has demonstrated the ORF of bacteriophage 77 only and its expression in *Staphylococcus aureus* in Examples 1-6, pages 60-66. Several bacteriophages against pathogenic bacteria have been listed in Table 1 and at page 26 specification indicates that bacteriophage are more preferably selected from bacteriophage 77, 3A and 96, however the specification fails to describe or demonstrate the invention as claimed in claims 107-113, for example determining a bacterial target for any plurality of bacteriophage ORF products (claims 107-111); for any plurality of targets (claim 112); or any plurality of different bacteria (claim 113).

Therefore, in view of the degree of guidance given in the specification and the limited exemplification of the method using bacteriophage inhibitor protein, coupled with the unpredictability associated with sequence prediction based on activity, it would require undue experimentation for a person having ordinary skill in the art to be able to practice the claimed invention without further guidance. Therefore, claims 100-115 stand rejected under 35 U.S.C. 112, first paragraph.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

Rita Mitra, Ph.D.
July 9, 2002